(e) if so, names of the members along with designation of each;

(f) whether it is a fact that his Ministry has forwarded the list of Department of Chemicals for price control under category I;

(g) if so, by when those drugs will be announced for price control;

(h) whether Government is reconsidering the drugs which have been omitted for inclusion; and

(i) if so, by when the additional list will be forwarded?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (i) Essential Drug list which comprised the drugs required for diseases covered under National Health Programmes has not yet been finalised.

Marketing of Quadruple vaccine in India

441. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to the answer to Unstarred Question 130 given in Rajya Sabha on 15th April, 1987 and state:

(a) whether quadruple vaccine is being marketed for the first time in the country;

(b) whether it is a fact that so far our country is concerned, it is treated to be new vaccine;

(c) if so, how food and drug Administration has granted the marketing permission of this vaccine in the counrry;

(d) what is the procedure for marketing of new vaccines and new drugs in the country;

(e) whether FDA Maharashtra has the authority to give marketing permission of new Drug and Vaccine; and

(f) if so, under what provision of Drugs and Cosmetics Act/Rules?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) Yes, Sir. Food and Drug Administration, Maharashtra has granted licence for marketing of combination of DPT with injectionable polio.

(b) According to Drug Controller of India, it is to be treated as a new vaccine as quadruple vaccine is still under clinical trial.

(c) Food and Drug Administration, Maharashtra, has been requested to withdraw the permission granted to market this vaccine.

(d) The procedure for granting marketing permission of a new drug includes examination of pre-clinical and clinical data pertaining to the safety and efficacy of the drug, examination of local clinical trial reports in many cases and consultation with medical experts of different disciplines. The status of the drug in other countries, the recognition of the use of the drug in official books and journals also consitute criteria for clearance of new drugs.

(e) and (f) No, Sir.

Essential drugs at reasonable prices

442. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Government have drawn a list of essential drugs;

(b) if so, what is the total number of drugs;

(c) whether it is a fact that the list has been drawn with the purpose to make medicines based on these drugs freely available at reasonable prices;

(d) if so, whether Government have forwarded the list to Ministry of Industry for covering under price control; and

(e) if so, by when the same will be covered under price control and consumer can get at reasonable prices?